NATIONAL PBM BULLETIN

August 31, 2015

DEPARTMENT OF VETERANS AFFAIRS
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP),
VISN PHARMACIST EXECUTIVES (VPEs), AND THE CENTER FOR MEDICAL SAFETY (VA MedSAFE)

LOSS OF DRUG POTENCY WITH ADVANCED PREPARATION AND STORAGE OF MEDICATIONS USING BECTON-DICKINSON (BD) 3mL and 5mL SYRINGES

I. ISSUE

FDA warns health care professionals not to administer to patients any compounded and repackaged drugs prepared and stored using Becton-Dickinson (BD) 3 milliliter (mL) and 5mL syringes due to loss of drug potency.

II. BACKGROUND

FDA and ISMP reports loss of potency with certain medications prepared in advance using 3mL or 5mL BD syringes. ISMP states that potency issues have not been identified with BD 1mL, 10mL, and larger syringes, although per FDA , BD's 10mL, 20mL, and 30mL syringes may also contain the same rubber stopper implicated in the issue. FDA cleared these 3 mL and 5 mL syringes for the general purposes of fluid aspiration and injection only. FDA has not established suitability of these syringes for any other purpose, such as closed-container storage systems for drug products. This warning may extend to other general use syringes made by other manufacturers not cleared for the purpose of closed-container storage use, but does not apply to products approved by FDA for marketing as pre-filled syringes.

III. DISCUSSION

Preliminary information suggests that the loss of potency is:

- Related to an interaction between the black rubber stopper from a secondary supplier that affects "pH sensitive" medications including, but not limited to, fentanyl citrate, methadone hydrochloride, morphine and atropine.
- Time dependent, with greater deterioration over time.
    - According to ISMP, laboratory testing of diluted fentanyl prepared in affected syringes showed variations in potency suggesting inadequate analgesia:
        - 3 syringes of diluted fentanyl 10mcg/mL progressively declined in potency from an average of 67% at 48 hours to 55% by day 6;
        - Fentanyl 5mcg/mL prepared in 3mL syringes held potencies that ranged between 10% and 70%.
    - FDA does not have any information on how long drugs can be stored before degrading or on whether any degradation occurs if medication is administered promptly after the syringes are filled.

IV. PROVIDER CONSIDERATIONS/RECOMMENDATIONS

FDA recommends that:

- Health care professionals should not use these general purpose syringes as closed-container systems for compounded and repackaged drugs.
- Hospital and pharmacy staff should check supply stocks and remove drug products that were filled by pharmacies or outsourcing facilities and stored in general purpose BD 3ml and 5ml syringes.
- Health care providers should not administer to patients compounded or repackaged drugs that have been stored in 3mL and 5mL syringes manufactured by BD unless there is no suitable alternative available. If no suitable alternative is possible, ISMP

(continued on page 2)

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recommends that hospitals using BD 3mL and 5mL syringes should prepare medication syringes as close to the time of administration as possible.

- If your facility has been using medications packaged in affected syringes, be aware that switching to an unaffected product may require a dose adjustment in case the patient has been receiving a subpotent preparation (e.g., as might potentially occur with a patient receiving an opioid).

V. REFERENCES

1. FDA Drug Safety and Availability: FDA warns health care professionals not to use compounded or repackaged drugs stored in Becton-Dickinson (BD) 3 milliliter (ml) and 5 ml syringes unless there is no suitable alternative available. http://www.fda.gov/Drugs/DrugSafety/ucm458952.htm . (Accessed 08/19/2015).

2. Institute for Safe Medication Practices. Special Alert: Loss of drug potency. *ISMP Medication Safety Alert! Acute Care*. August 13, 2015. 20 (15):1-2.

ACTIONS

- ***Facility Director*** *(or physician designee): Forward this document to the Facility Chief of Staff (COS).*
- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers and health care staff (e.g.,* ***primary care providers, pain specialists, pharmacy staff, including contract providers, etc****.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.*
- ***ACOS for R&D:*** *Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).*